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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,308	09/01/2004	Atsushi Nakanishi	3030 US0P	8302

23115 7590 09/21/2006

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,308	NAKANISHI ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,27,28,31-34 and 37-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24, 27-28, 31-34, and 37-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, 14, and 37, drawn to a protein or a pharmaceutical composition comprising said protein.

Group 2, claim(s) 8-13, 15-16, 20-22, 40, and 42, drawn to nucleic acids encoding a protein of Group I, transformed cells, and pharmaceutical compositions comprising a nucleic acid.

Group 3, claim(s) 17-19 and 41, drawn to an antibody for a protein of Group 1.

Group 4, claim(s) 23-24, drawn to a method of screening a compound that promotes or inhibits the activity of a protein of Group 1, with said method comprising using the protein of Group I, and a kit for screening a compound.

Group 5, claim(s) 27-28, drawn to a method of screening a compound that promotes or inhibits the expression of a gene for a protein of Group 1.

Group 6, claim(s) 31-32, drawn to methods of quantifying a protein of Group 1 and of diagnosing diseases associated with the function of a protein of Group 1.

Group 7, claim(s) 33-34, drawn to a method of screening a compound that promotes or inhibits the activity of a protein of Group 1, with said method comprising using the antibody of Group 3, and a kit for screening a compound.

Group 8, claim(s) 38, drawn to a method of preventing/treating renal diseases.

Group 9, claim(s) 39, drawn to a method for making a prophylactic/therapeutic agent.

B. The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The first claimed invention fails to share a special technical feature with the other claims. PCT rules define a special technical feature as a feature that makes a contribution over the art. Claim 1 has no such special technical feature in view of Curtis *et al* (US 6,972,187). Claim 1 is drawn to a protein comprising the same or substantially the same amino acid sequence as an amino acid sequence represented by SEQ ID NOs 1, 26, or 52. Curtis *et al* teaches a polypeptide with 99.9% sequence identity to SEQ ID NO: 1 of the instant application. The specification of the instant application, on page 8, line 32 – page 9, line 3, defines a protein that is "substantially" the same amino acid sequence as one "having at least about 50% homology.....to the amino acid sequence represented by SEQ ID NO: 1". Because Curtis *et al* therefore specifically teaches a protein having substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, claim 1 cannot share a special technical feature with the other claims.

C. Additionally, groups 1-9 are subject to further restriction. It is noted that the claims are drawn to examination of at least one of a number of structurally distinct polypeptides or nucleic acids. Specifically, groups 1-9 are drawn to the proteins having the polypeptide sequence represented by SEQ ID NOs 1, 26, or 52, nucleic acids encoding said proteins, or methods of using said proteins or nucleic acids. Accordingly, in order to be fully responsive, Applicants are required to elect a specific polypeptide sequence selected from SEQ ID NO: 1, SEQ ID NO: 26, or SEQ ID NO: 52. This is NOT an election of species. The claimed polypeptide or nucleic acid

sequences are structurally distinct chemical compounds, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such polypeptide or nucleic acid sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CRF 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct polypeptide or nucleic acid sequences represents a serious burden for the office.

D. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

E. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

F. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

G. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

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